

## **Remarks**

### **In the Claims**

Claims 26, 27, 29-42, 44-50, 52-65 and 67-71 are currently pending in the application. Note that claim 28 was previously canceled. As discussed in greater detail below, Applicant traverses the rejections made in the Office Action, and no claims have been amended.

### **Rejection under 35 U.S.C. §102**

The Office Action rejected claims 26, 35-36, 38, 41-42, 44-49, 57-59, 61-65 and 69 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent no. 6,610,040 to Fowles et al. ("Fowles"). Applicant respectfully traverses.

A similar rejection on this basis was made in the December 10, 2009 Office Action. Then as now, the Office Action cited columns 1-13 and the claims in Fowles as support for the rejection. With all due respect, this amounts to virtually the entire Fowles specification, with the Office Action failing to point out with particularity how Fowles anticipates each and every element of the claims of the instant application.

For example, Fowles at least does not disclose, among other elements in the claims, a container spiking assembly controller in communication with the container spiking assembly for controlling coupling of the container receptacle with the port assembly, as recited in claim 26. Nor does Fowles disclose a positioning means for moving the container receptacle toward the port assembly, as recited in claim 49 (at least not a positioning means in the sense disclosed in the instant application).

Applicant has not found within Fowles any disclosure of at least the above features as recited in the independent claims of the instant application. In fact, Fowles discloses a different method of coupling a vial with a spike assembly. For example, Fowles describes the operation of its device as follows: "...the port 20 of the flexible bag 12 is inserted into the central channel 35 of the first sleeve member 30." "...the cannula 34 will puncture the septum 22 of the flexible bag 12." "The medical professional will .. fixedly dock the vial 14 into the receiving chamber 86." "...the medical professional will then rotate the first sleeve 30 in relation to the second

sleeve 32, to place the device 10 in the unlocked position.” “...the medical professional will move the first sleeve 30 axially in relation to the second sleeve 32 until the bushing 52 abuts the uppermost end 122 of the second sleeve member 32 causing an end of the cannula to puncture the rubber stopper 24 of the vial 4.” (Fowles col. 12 ll. 51-67; col. 13 ll. 1-10).

“To anticipate a claim, the reference must teach every element of the claim.” (MPEP s. 2131) As shown above, Fowles fails to disclose each element of independent claims 26 and 49, and Fowles therefore cannot anticipate those claims. Because the independent claims are not anticipated by Fowles, none of the dependent claims in the instant application can be anticipated by Fowles. Withdrawal of the rejection under 35 U.S.C. §102 of claims 26, 35-36, 38, 41-42, 44-49, 57-59, 61-65 and 69 is respectfully requested.

#### **Rejection under 35 U.S.C. §103**

The Office Action rejected claims 26-34, 37, 39-40, 50, 52-56, 60, 67-68, 70-71 under 35 U.S.C. §103(a) as being unpatentable over Fowles in view of U.S. Patent no. 6,070,761 to Bloom et al. (“Bloom”). Applicant respectfully traverses.

The Office Action stated that Bloom discloses a vial loading method and apparatus “for intelligent admixture and delivery” of intravenous drugs using pneumatic controller means. However, the Office Action appears to misidentify an element in Bloom that is important in sustaining the rejection. It identifies a “controller 207 for controlling coupling of the container and the port assembly (col. 17, ll. 8-26).” In fact, Bloom does not disclose a controller 207 for controlling coupling of the container and the port assembly. As the Office Action itself stated twice, element 207 refers to a holder: a “holder (207) movable between an unlocked position where the vial does not contact the spike, and a locked position in which it does contact the spike,” and that “[s]everal holders (207) are mounted on a panel (202).”

Furthermore, the section of Bloom cited by the Office Action to support its rejection – column 17, lines 8-26 – actually discusses a fluid delivery module 88 possessing an acoustic volume sensing technology for detection of air in a pressure conduction chamber. Bloom does disclose a holder 207 that is part of a vial loading mechanism 200 (col. 18 ll. 21-43). However, in that case, “[t]he clinician forces the holder 207 to be lowered so that the spike 118 pierces the

membrane seal 120 of the vial 85.” (col. 19 ll. 38-40). Considering the Office’s misidentification of element 207 in Bloom, and Bloom’s actual description of the mechanism of spiking a vial, the Office Action has failed to show how Bloom discloses a controller for controlling coupling of a container receptacle with a port assembly.

Thus, neither Bloom nor Fowles – either alone or in combination – teach, suggest or predict a container spiking assembly controller in communication with a container spiking assembly for controlling coupling of a container receptacle with a port assembly (claim 26), or a positioning means for moving the container receptacle toward the port assembly (claim 49) (at least not a positioning means in the sense disclosed in the instant application).

“When evaluating claims for obviousness under 35 U.S.C. 103, all the limitations of the claims must be considered and given weight...” (MPEP §2143.03). Among other reasons, the controller recited in the claims and discussed above is not a predictable result from combining the teaching of Fowles with Bloom, because the mechanism of operation of the apparatus in either reference is not readily amenable to implementing such a controller. In addition, there is no substitution of known elements in either reference that predicts the controller. Furthermore, neither Fowles nor Bloom establishes a known technique that would result in the implementation of such a controller. For at least these reasons, a prima facie case of obviousness of claims 26 and 49 has not been established. And since the independent claims are nonobvious, “then any claim depending therefrom is nonobvious” (MPEP §2143.03). Therefore, withdrawal of the rejection under 35 U.S.C. §103 of claims 26-34, 37, 39-40, 50, 52-56, 60, 67-68, and 70-71 is respectfully requested.

**Conclusion**

For the foregoing reasons all of the claims of the present invention are patentable over the art of record. It is believed that all of the claim rejections have been addressed and that the application is now in condition for allowance. Reconsideration of the claims and issuance of a notice of allowance are respectfully requested. If any matter arises for which an interview may expedite issuance of a notice of allowance, the Examiner is requested to call the undersigned at the telephone number given below.

Applicants do not believe that an extension of time is required. However, if an extension of time is, in fact, required, Applicants request that the associated extension fee be charged to Deposit Account No. 50-4383. Applicants also request that any other fee required for timely consideration of this application be charged to Deposit Account No. 50-4383.

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Respectfully submitted,

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